



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

SEP 25 2002

Kenneth I. Burke, PhD, RD  
Professor/Associate Chairman  
Loma Linda University  
School of Allied Health Professions  
Department of Nutrition and Dietetics  
Loma Linda, California 92350

Dear Dr. Burke:

This letter is in response to your letter dated September 11, 2002, to Michael A. Adams, in which you support the health claim petition submitted by the California Walnut Commission.

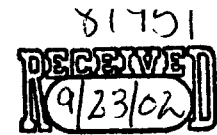
We appreciate your interest in the issues raised in the health claim petition. We have forwarded your letter to the Dockets Management Branch (HFA-305) for inclusion in the administrative record under Docket No. 02P-0292. Your letter will be considered by the agency in its deliberations on what action to take on the California Walnut Commission's health claim petition.

Sincerely,

James E. Hoadley, Ph.D.  
Team Leader for Nutrition Labeling and Programs  
Division of Nutrition Science and Policy  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

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## LOMA LINDA UNIVERSITY

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*September 11, 2002*

Michael A. Adams, PhD  
Acting Director, Division of Nutrition Science and Policy  
Office of Nutritional Products, Labeling, & Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD  
20740-3835

RE: Letter of support for walnut health claim: docket #02p-0292

Dear Dr. Adams:

I support the conclusions of the well designed, extensive research that demonstrates the positive effects of walnut consumption on the coronary heart disease risk factors.

The prospective epidemiologic study among California Adventists clearly showed that frequent nut consumption was associated with a substantial, independent reduction in the risk of myocardial infarction and death from ischemic heart disease (Fraser GE, Sabate J, Beeson WL, Straham TM. A possible protective effect of nut consumption on risk of coronary heart disease: the Adventist Health Study. Arch Intern Med 1992;152:1416-24).

In addition a human feeding study with a cross-over design strongly demonstrated that incorporating walnuts into the recommended cholesterol-lowering diet while maintaining the intake of total dietary fat and calories decreased serum levels of total cholesterol and favorably modified the lipoprotein profile in normal men (Sabate J, Fraser GE, Burke K, Knutsen SF, Bennett H, Lindsted KD. Effects of walnuts on serum lipid levels and blood pressure in normal men. N Engl J Med 1993;328(9):603-7)

A third, randomized crossover, study substituted about 35% of energy derived from for monounsaturated fat in a cholesterol-lowering Mediterranean diet with walnuts in the diets of polygenic hypercholesterolemic men and women. This diet modification resulted in significantly lowering of total and LDL cholesterol (Zambon D, Sabate J, Munoz S, Campero B, Casals E, Merlos M, Laguna JD, Ros E. Substituting walnuts for monounsaturated fat improves the serum lipid profile of hypercholesterolemic men and women. Ann Intern Med 2000;132(7):538-546).

These and other studies clearly demonstrate the public health importance of nut consumption in general and walnuts in particular. Although all the components of walnuts that favor good heart health are not known, the somewhat unique profile of a near ideal ratio of omega-3 to omega-6 fatty acids plays a significant role (see above citation)(The September 5, 2002 news release of the Food and Nutrition Board of the National Academies underscores the recommendation of omega-3 and omega-6 consumption). Undoubtedly walnuts' favorable heart-healthy action is not limited only to its fatty acid composition.

It is my professional opinion that public interest and the public health would be well served by promoting the increased consumption of walnuts through a scientifically well supported health claim.

Sincerely yours,

A handwritten signature in black ink that reads "Kenneth I. Burke". The script is cursive and fluid.

Kenneth I. Burke, PhD, RD  
Professor/Associate Chairman